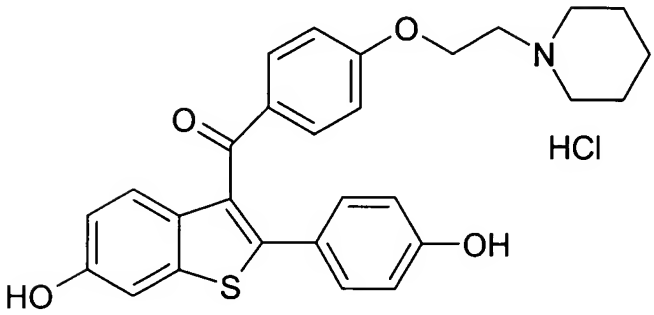
IN THE CLAIMS:

1.-25. (Cancelled)

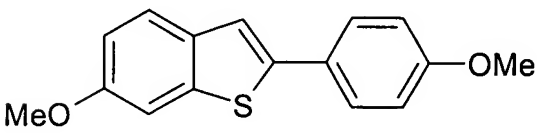
26. (Currently amended) Process for preparing raloxifene hydrochloride of formula (I)



(I)

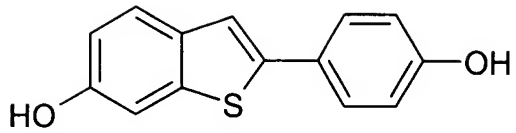
with a HPLC purity higher than 98% comprising the following stages:

a) demethylation of 6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene of formula (II)



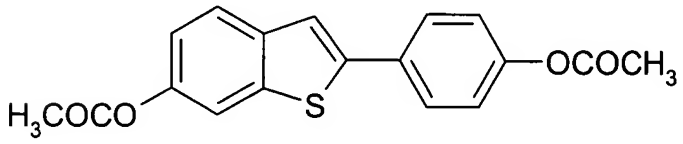
(II)

in pyridine hydrochloride to obtain 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophene of formula (III)



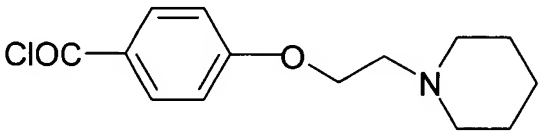
(III)

b) acetylation of 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophene with an acetylating agent to obtain the corresponding 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene of formula (IV)



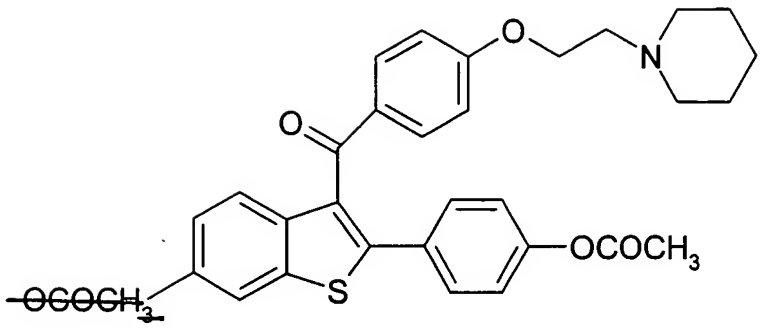
(IV)

c) acylation of 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene (IV) with 4-(2-piperidinoethoxy)benzoylchloride hydrochloride of formula (V)

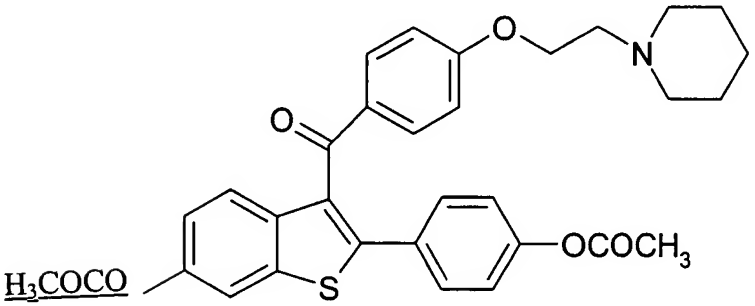


HCl

with aluminium chloride in halogenated solvent to obtain 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[t(V)ophene of formula (VI)



(VI)



(VI)

d) hydrolysis of 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[b]thiophene, according to the following operative modalities:

d1) treatment of 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[b]thiophene with alkaline hydroxide in alcohol solvent,

d2) acidification of the product obtained in the preceding stage (d1) with a strong acid, to obtain the corresponding raloxifene salt with the strong acid,

wherein:

stage (d1) is conducted using methanol as alcohol solvent and excess 30% sodium hydroxide,

27. (New) Process as claimed in claim 26, wherein the pyridine hydrochloride used in stage (a) is prepared in situ by adding concentrated hydrochloric acid to pyridine and distilling off all the water to obtain a thick but stirrable residue.

28. (Currently Amended) Process as claimed in claim 26, wherein the demethylation reaction ~~or~~ of stage (a) of the process of the present invention is also conducted in the presence or tributylamine.

29. (Currently Amended) Process as claimed in claim 28, characterised in that tributylamine is used ~~preferably~~ in weight ratios with respect to 6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene (II) of between 0.5 and 2.

30. (Previously Presented) Process as claimed in claim 29, characterised in that stage (a) is conducted at a temperature between 170 and 180°C.

31 (Previously Presented) Process as claimed in claim 26, wherein acetic anhydride is used as acetylating agent in the presence of triethylamine in ethyl acetate.

32. (Previously Presented) Process as claimed in claim 26, wherein the 4-(2-piperidinoethoxy)benzoylchloride hydrochloride of formula (V) used in stage (c) is prepared in situ, by reacting 4-(2-piperidinoethoxy)benzoic acid hydrochloride with thionyl chloride in methylene chloride in the presence of pyridine, without isolating the reaction product.

33. (Previously Presented) Process as claimed in claim 26, wherein stage (c) is conducted in methylene chloride.

34. (Previously Presented) Process as claimed in claim 33, wherein stage (c) is conducted according to the following operative modalities: 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene (IV) is added to non-isolated 4-(2-piperidinoethoxy)benzoylchloride hydrochloride of formula (V) and prepared in situ as in

claim 7 and the aforesaid mixture is poured onto a mixture consisting of methylene chloride and aluminium trichloride.

35. (Previously Presented) Process as claimed in claim 26, wherein the 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene (IV) is not isolated, but is used in the crude state in the subsequent reaction (d).

36. (Previously Presented) Process as claimed in claim 26, wherein raloxifene hydrochloride derived from stage (d2) is crystallised from an alcoholic solvent.

37. (Currently Amended) Process as claimed in claim 36, wherein said solvent is methanol ~~possibly~~ in the presence of HCl.

38. (Previously Presented) Process as claimed in claim 36, wherein raloxifene hydrochloride is obtained with a purity greater than 99%.

39. (Previously Presented) Process as claimed in claim 36, wherein a further crystallisation from raloxifene hydrochloride from alcohol solvent is conducted.

40. (Currently Amended) Process as claimed in claim 39, wherein said crystallisation is conducted in methanol possibly in the presence of HCl.

41. (Previously Presented) Raloxifene hydrochloride with a purity greater than 99.7% and containing aluminium in a quantity less than 5 ppm %.

42. (Previously Presented) Raloxifene hydrochloride as claimed in claim 41, containing raloxifene hydrochloride N-oxide in a quantity less than 0.05%.

43. (Previously Presented) Raloxifene hydrochloride as claimed in claim 42, wherein said impurity is contained in a quantity less than 0.01%.

44. (Previously Presented) Raloxifene hydrochloride as claimed in claim 43, having a D(0.9) ≤100μm and a D(0.5) ≥40μm.

45. (Previously Presented) Raloxifene hydrochloride as claimed in claim 44, having a D(0.9) between 50 and 65 μm and a D[4.3] ≥20μm.